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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/835,482	04/08/97	RUBIN A	002

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EXAMINER	
SEIDLECK,B	
ART UNIT	**PAPER NUMBER**
1615	21

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Please find below and/or attached an Office communication concerning this application or proceeding.

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UNITED STATES DEPARTMENT OF COMMERCE
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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Paper No. 21

Application Number: 08/835,482
Filing Date: April 8, 1997
Appellant(s): Rubin

Gildo E. Fato Reg. No. 20,962
For Appellant

EXAMINER'S ANSWER

This is in response to appellant's supplemental brief on appeal filed May 10, 2000.

(1) Real Party in Interest

A statement identifying the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

A statement identifying the related appeals and interferences which will directly affect

or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief.

(3) Status of Claims

The statement of the status of the claims contained in the brief is correct. This appeal involves claims 1, 11 and 12.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Invention

The summary of invention contained in the brief is correct.

(6) Issues

The appellant's statement of the issues in the brief is correct.

(7) Grouping of Claims

Appellant's brief includes a statement that the claims stand or fall together.

(8) Claims Appealed

The copy of the appealed claims contained in the Appendix to the brief is correct.

(9) Prior Art of Record

The following is a listing of the prior art of record relied upon in the rejection of claims under appeal.

4,900,755	DEMPSKI et al.	2-1990
5,738,874	CONTE et al.	4-1998

(10) Grounds of Rejection

The following grounds of rejection are applicable to the appealed claims:

A. Claims 1, 11 and 12 are rejected under 35 U.S.C. § 103(a) as being unpatentable over the combined teachings of Dempski et al (U.S. Pat. No. 4,900,755, collectively "Dempski") and Conte et al (U.S. Pat. No. 5,738,874, collectively "Conte").

Dempski teaches the combination of levodopa and carbidopa in a sustained release formulation. See abstract. This combination is well known in the art for the treatment of Parkinson's disease, commercially available as Sinemet®. See Dempski at Col. 1, lines 18-60.

The art recognizes the importance of treating Parkinson's disease with a dosage form which prevents the emergence of "wearing-off" and "on-off" phenomena. See Dempski at Cols. 1-2. As to the overall concentrations of the drugs, Dempski teaches overlapping ranges at Col. 3, lines 45-60. It is well known in the art that the overall dosage will vary depending on the weight, age and severity of the condition being treated. It remains the examiner's position that the amount of drugs used in the present invention are known in the art for treating Parkinson's and it would have been obvious for one skilled in the art to regulate the dosage based on the individual patient being treated.

Conte teaches a pharmaceutical tablet capable of releasing one or more drugs, including levodopa and carbidopa, at different release rates. See abstract; Cols. 2-3; and Cols. 17-18, claims 1 and 6. The first layer contains one or more drugs with an immediate release profile and a second layer containing one or more drugs with a sustained release profile. Id. Conte teaches a pharmaceutical tablet capable of releasing one or more drugs at different release rates in either a two layered or three layered formulation. See abstract and drawings. The first layer contains one or more drugs with an immediate release profile and a second layer containing one or more drugs with a sustained release profile. See abstract; and Cols. 2-3. An optional barrier can be placed between the first and second layers. See abstract.

(11) Response to Argument

The applicant asserts that the present invention has solved the problems of the prior art by providing an effective formulation having both immediate and sustained release properties to

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Brian K. Seidleck** whose telephone number is **(703) 305-4448**. The examiner can normally be reached **Monday through Friday from 6:30am to 4:00pm**.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's **supervisor, Thurman K. Page**, can be reached on **(703) 308-2927.** The official fax numbers for Technology Center 1600 are (703) 305-3592 and (703) 308-4556. The unofficial fax number is (703) 308-7921.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. § 132 or which otherwise require a signature, may be used by the applicant and should be addressed to **[thurman.page@uspto.gov].**

All Internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of confidentiality requirements of U.S.C. § 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Technology Center receptionist whose telephone number is (703) 308-1235 or (703) 308-1234.

provide immediate and long lasting therapeutic action of carbidopa-levodopa to treat Parkinson's disease. However, the examiner notes that the present specification contains no data to demonstrate this claimed improvement over the prior art for the treatment of Parkinson's. Thus, it remains the examiner's position that applicant has not provided unexpected results to demonstrate an improvement over the prior art of record to overcome the above obviousness rejection. As stated above, it is well known in the art that formulations containing both an immediate and sustained release profile allow for the active(s) to enter the bloodstream quickly and to maintain an effective concentration over an extended period of time.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
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BKS
Brian K. Seidleck
May 17, 2000

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